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# TRANSMITTAL OF APPEAL BRIEF (Small Entity)

Docket No.
**MSU 4.1-458**

In Re Application Of: **Linda S. Mansfield, Mary G. Rossano, Alice J. Murphy, and Ruth A. Vrable**

| Application No. | Filing Date | Examiner | Customer No. | Group Art Unit | Confirmation No. |
|---|---|---|---|---|---|
| 09/513,086 | February 24, 2000 | Joseph T. Woitach | 21036 | 1632 | 4724 |

Invention: **VACCINE TO CONTROL EQUINE PROTOZOAL MYELOENCEPHALITIS IN HORSES**

COMMISSIONER FOR PATENTS:

Transmitted herewith is the Appeal Brief in this application, with respect to the Notice of Appeal filed on:

**March 3, 2006**

☒ Applicant claims small entity status. See 37 CFR 1.27

The fee for filing this Appeal Brief is: **$250.00**

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*Signature*

Dated: **March 6, 2006**

**Ian C. McLeod**
**Registration No. 20,931**
**McLeod & Moyne, P.C.**
**2190 Commons Parkway**
**Okemos, Michigan 48864**
**(517) 347-4100**
**Fax: (517) 347-4103**

cc:

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*(Date)*

Tammi L. Taylor

*Signature of Person Mailing Correspondence*

**Tammi L. Taylor**

*Typed or Printed Name of Person Mailing Correspondence*

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Appl. No. : 09/513,086 Confirmation No. 4724

Applicants : Linda S. Mansfield, Mary G. Rossano, Alice J. Murphy, and Ruth A. Vrable

Filed : February 24, 2000

Title: VACCINE TO CONTROL EQUINE PROTOZOAL MYELOENCEPHALITIS IN HORSES

TC/A.U. : 1632

Examiner : Woitach, Joseph T.

Docket No. : MSU 4.1-458

Customer No. : 21036

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Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

**BRIEF UNDER 37 C.F.R. § 41.37**

Sir:

This is an appeal from a final rejection in the above entitled application. The claims on appeal are set forth as Claims Appendix. An oral hearing will be requested. Enclosed is the fee due upon filing of the Brief.

## (1) Real Party in Interest

The real party in interest is the Board of Trustees operating Michigan State University, East Lansing, Michigan, a constitutional corporation of the State of Michigan, which is the assignee of the above entitled application.

## (2) Related Appeals and Interferences

The present application is Application Serial No. 09/513,086 ('086), filed February 24, 2000, and which claims benefit of a provisional patent Application No. 60/152,193, filed September 2, 1999.

This application is related to Application Serial No. 09/669,833 ('833) which relates to a method for producing an antibody for use as a passive immunity vaccine in horses against a *Sarcocystis neurona* antigen selected from the group consisting of a 16 (+/-4) kDa antigen and a 30 (+/-4) kDa antigen; Application Serial No. 09/669,843 ('843) which relates to a monoclonal antibody which selectively binds to a *Sarcocystis neurona* antigen; Application Serial No. 09/670,096 ('096), relating to

compositions and method for treating an equid infected with *Sarcocystis neurona* with antibodies against the 16 ±4 and 30 ±4 kDa antigens; Application Serial No. 09/670,244 ('224) which relates to recombinant protein comprising the 16 ±4 and 30 ±4 kDa antigens; and Application Serial No. 09/670,355 ('355), relating to a vaccine comprising DNA encoding the 16 ±4 and 30 ±4 kDa antigens. The above applications were all filed on September 26, 2000.

The '355 application and the '244 application have been abandoned. Application Serial No. 09/670,096 ('096) and Application Serial No. 09/669,833 ('833) are on appeal. No application has been allowed. There are no other related appeals and interferences.

**(3) Status of Claims**

Claims 4, 13, 46 and 50 are pending in the application. Claims 1-3, 5-12, 14-45, 47-49 were cancelled. Claims 4, 13, 46 and 50 were rejected. No claims have been allowed. Claims 4, 13, 46 and 50 are on appeal.

## (4) Status of Amendments

No amendments have been filed subsequent to final rejection.

## (5) Summary of Claimed Subject Matter

The claimed subject matter in Claim 4 is a composition consisting of a single naturally occurring 16 (±4) kDa protein antigen isolated from *Sarcocystis neurona* and a single naturally occurring 30 (±4) kDa protein antigen isolated from *Sarcocystis neurona* in a pharmaceutically accepted carrier. Support for this claim is found in Example 1, page 33, lines 25-34.

The claimed subject matter in Claim 13 is a method for treating an equine with a *Sarcocystis neurona* infection comprising: (a) providing a composition consisting of a single naturally occurring 16 (±4) kDa protein antigen isolated from *Sarcocystis neurona* and a single naturally occurring 30 (±4) kDa protein antigen isolated from *Sarcocystis neurona* in a pharmaceutically accepted carrier; and (b) inoculating the equine with the composition to treat the equine with the *Sarcocystis neurona* infection. Support

for this claim is found in Example 1, page 33, lines 25-34. Support for using the vaccine as a vaccine for an equine is found at page 13, lines 1-5. Support for inoculating the equine is found at page 14, lines 32 to page 15, line 25.

The claimed subject matter in Claim 46 is a method for treating a disease in an equine caused by a *Sarcocystis neurona* infection which comprises providing a composition which when injected into the equine causes the equine to produce antibodies against a 16 (±4) kDa antigen and a 30 (±4) kDa antigen of the *Sarcocystis neurona* which treats the disease caused by the *Sarcocystis neurona,* wherein the composition consists of a single naturally occurring 16 (±4) kDa protein antigen isolated from *Sarcocystis neurona* and a single naturally occurring 30 (±4) kDa protein antigen isolated from *Sarcocystis neurona* in a pharmaceutically accepted carrier. Support for this claim is found in Example 1, page 33, lines 25-34. Support for using the vaccine as a vaccine for an equine is found at page 13, lines 1-5. Support for inoculating the equine is found at page 14, lines 32 to page 15, line 25. Support for treatment is found at page 10, lines 22-34. Support for causing the equine to produce antibodies is found at page 9,

lines 22-31.

The claimed subject matter in Claim 50 is a method of Claim 46 wherein the composition is administered by an inoculation route selected from the group consisting of intranasal administration, intramuscular injection, intraperitoneal injection, intradermal injection, and subcutaneous injection. Support for this claim is found in Example 1, page 33, lines 25-34. Support for using the vaccine as a vaccine for an equine is found at page 13, lines 1-5. Support for inoculating the equine is found at page 14, lines 32 to page 15, line 25. Support for the route of administration is found at page 13, lines 24-35.

## (6) Grounds of Rejection to Be Reviewed on Appeal

(A) The Examiner rejected Claims 4, 13 and 46 under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

(B) The Examiner rejected Claims 4, 13 and 46 under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, since a disclosure cannot teach one to make or use something that has not been described.

(C) Claims 4, 13, 45, 46 and 50 were rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

## (7) Argument

(A) The Examiner rejected Claims 4, 13 and 46 under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

The subject matter of a claim need not be described literally (*i.e.*, using the same terms or *in haec verba*) in order for the disclosure to satisfy the description requirement (MPEP §2163.02). While the term "naturally occurring" is not found in the text, according to Example 1 on page 33 of the specification:

> "*Sarcocystis neurona* was cultured on equine dermal cell line cultures as taught in Example 3 or on bovine monocyte cell cultures as taught by Granstrom *et al.*, *J. Vet. Diagn. Invest.* 5: 88-90 (1993). *Sarcocystis neurona* merozoites were harvested and the 16 (±4) kDa antigen and/or 30 (±4) kDa antigen were purified by methods known to the art for purifying antigens, i.e., the 16 (±4) kDa antigen and/or 30 (±4) kDa antigen were purified from merozoites by two-dimensional polyacrylamide gel electrophoresis. Then the purified antigens are used to make monoclonal antibodies according to the methods in *Antibodies, A Laboratory Manual*, eds. Harlow and Lane, Cold Spring Harbor Laboratory Press, Cold Spring Harbor, New York (1988),

well known to those skilled in the art as a source for methods for making polyclonal and monoclonal antibodies."

According to MPEP §2163.02, whenever the issue arises, the fundamental factual inquiry is whether the specification conveys with reasonable clarity to those skilled in the art that, as of the filing date sought, applicant was in possession of the invention as now claimed. *See, e.g., Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991). An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997). Possession may be shown in a variety of ways including description of an actual reduction to practice, or by showing that the invention was "ready for patenting" such as by the disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention. *See, e.g., Pfaff v.*

*Wells Elecs., Inc.*, 525 U.S. 55, 68, 119 S.Ct. 304, 312, 48 USPQ2d 1641, 1647 (1998); *Regents of the University of California v. Eli Lilly*, 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997); *Amgen, Inc. v. Chugai Pharmaceutical*, 927 F.2d 1200, 1206, 18 USPQ2d 1016, 1021 (Fed. Cir. 1991) (one must define a compound by "whatever characteristics sufficiently distinguish it"). As seen in Example 1, the 16 (±4) kDa antigen and 30 (±4) kDa antigen are purified from *Sarcocystis neurona* cultures and are thus naturally occurring proteins isolated from *Sarcocystis neurona*. In this example, mice are injected with the purified 16 (±4) kDa antigen and 30 (±4) kDa antigen to produce antibodies. Thus, the purified proteins are used as antigens for the production of antibodies. Therefore, the claimed subject matter was described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Reversal of the rejection is requested.

(B) The Examiner rejected Claims 4, 13 and 46 under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, since a disclosure cannot teach one to make or use something that has not been described.

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue." These factors include, but are not limited to:

(A) The breadth of the claims;
(B) The nature of the invention;
(C) The state of the prior art;
(D) The level of one of ordinary skill;
(E) The level of predictability in the art;
(F) The amount of direction provided by the inventor;
(G) The existence of working examples; and
(H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

*In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed.

Cir. 1988). The examiner's analysis must consider all the evidence related to each of these factors, and any conclusion of nonenablement must be based on the evidence as a whole. 858 F.2d at 737, 740, 8 USPQ2d at 1404, 1407.

Considering the state of the prior art of protein isolation, the direction provided by the inventors in Example 1, and the high level of one or ordinary skill in the art the subject matter was described in the specification in such a way as to enable one skilled in the art to make the invention. The quantity of experimentation needed to be performed by one skilled in the art is only one factor involved in determining whether "undue experimentation" is required to make and use the invention. "[A]n extended period of experimentation may not be undue if the skilled artisan is given sufficient direction or guidance." *In re Colianni*, 561 F.2d 220, 224, 195 USPQ 150, 153 (CCPA 1977). "The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed." *In re Wands*, 858 F.2d 731,

737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) (citing In re Angstadt, 537 F.2d 489, 502-04, 190 USPQ 214, 217-19 (CCPA 1976)). It is believed that the example provides sufficient information such that a person of ordinary skill in the art can make and/or use the invention.

M.P.E.P. 2164.01(b) states, that as long as the specification discloses at least one method for making and using the claimed invention that bears a reasonable correlation to the entire scope of the claim, then the enablement requirement of 35 U.S.C. 112 is satisfied. *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970). The 16 (±4) kDa antigen and 30 (±4) kDa antigen are each purified from *Sarcocystis neurona* cultures as described in Example 1. The specification specifically teaches in Example 1 that the 16 (±4) and 30 (±4) kDa antigens are isolated by two-dimensional gel electrophoresis (page 33, lines 29-34). These are therefore naturally occurring proteins which are isolated from *Sarcocystis neurona*. In addition, it is taught in Example 1 that mice can be injected with the purified 16 (±4) kDa antigen and 30 (±4) kDa antigen to produce antibodies. Therefore the specification enables one skilled in the art to make and/or

use the invention. Reversal of the rejection is requested.

(C) The Examiner rejected Claims 4, 13, 46 and 50 under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

An objective standard for determining compliance with the written description requirement is, "does the description clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed." *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989). Under *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991), to satisfy the written description requirement, an applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention, and that the invention, in that context, is whatever is now claimed. The test for sufficiency of support in a parent application is whether

the disclosure of the application relied upon "reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter." *Ralston Purina Co. v. Far-Mar-Co., Inc.*, 772 F.2d 1570, 1575, 227 USPQ 177, 179 (Fed. Cir. 1985) (quoting *In re Kaslow*, 707 F.2d 1366, 1375, 217 USPQ 1089, 1096 (Fed. Cir. 1983)). Whenever the issue arises, the fundamental factual inquiry is whether the specification conveys with reasonable clarity to those skilled in the art that, as of the filing date sought, applicant was in possession of the invention as now claimed. See, e.g., *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991).

The claimed composition consists of a single naturally occurring 16 (±4) kDa protein antigen isolated from *Sarcocystis neurona* and a single naturally occurring 30 (±4) kDa protein antigen isolated from *Sarcocystis neurona* in a pharmaceutically accepted carrier. The claimed methods utilize this composition to treat the equine with the *Sarcocystis neurona* infection. The composition consists of naturally occurring protein antigens which are isolated from *Sarcocystis neurona*, and is not directed to polypeptide fragments, recombinant polypeptides or fusion polypeptides.

As the claims are specifically directed to the isolated form of the naturally occurring proteins, it is believed that the written description requirement of 35 U.S.C. §112, first paragraph is satisfied.

The 16 (±4) and 30 (±4) kDa antigens are described in the specification by their physical properties, not merely by their function. The 16 (±4) and 30 (±4) kDa antigens are described by their source (isolated from *Sarcocystis neurona*), by their molecular weight as determined by SDS gel electrophoresis, by their ability to bind particular antibodies in antisera from horses infected with *Sarcocystis neurona*, and by their ability to bind monoclonal antibodies prepared against them. These physical properties convey sufficient information about the antigens to distinguish them from the other proteins of *Sarcocystis neurona*. There is no need to know the amino acid sequence of the antigens or the nucleotide sequence encoding the antigens to identify them. The specification describes the 16 (±4) and 30 (±4) kDa antigens by their respective mobilities on SDS polyacrylamide gels (Page 36, lines 22-27 of the specification; U.S. Serial No. 09/156,954, which is now U.S. Patent No. 6,153,394, incorporated by reference on

page 13, lines 16-17 of the specification) and two-dimensional gels (Specification: page 33, lines 29-34), by their ability to bind antibodies in antisera from horses infected with *Sarcocystis neurona* (U.S. Patent No. 6,153,394), and by their inability to bind antibodies from other *Sarcocystis* species (Page 13, lines 20-21 of the specification).

The specification further teaches in Example 1 that the 16 (±4) and 30 (±4) kDa antigens were isolated by two-dimensional gel electrophoresis (page 33, lines 29-34) and teaches a method for preparing monoclonal antibodies using the purified 16 (±4) and 30 (±4) kDa antigens. The monoclonal antibodies can be used to identify the 16 (±4) and 30 (±4) kDa antigens (Example 1 at page 33, line 20 of the specification). Therefore, a person of ordinary skill in the art following the teachings in the specification of the present application would be able to identify and isolate the 16 (±4) and 30 (±4) kDa antigens of *Sarcocystis neurona*. Furthermore, the applicants are not claiming the 16 (±4) and 30 (±4) kDa antigens *per se*. They are claiming a composition that consists of naturally occurring protein antigens, which can be isolated by described methods from a

known source. The written description is believed to be adequate without the necessity of providing the amino acid sequence of the proteins comprising the composition. Reversal of the rejection is requested.

B. Conclusion

As shown above, the claimed subject matter is described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors had possession of the claimed subject matter. Also, the claimed subject matter was described in the specification in such a way as to enable one skilled in the art to which it pertains to make and/or use the invention. Therefore, Claims 4, 13, 46 and 50 are patentable. Reversal of the Final Rejection is requested.

Respectfully,

Ian C. McLeod
Registration No. 20,931

McLEOD & MOYNE, P.C.
2190 Commons Parkway
Okemos, MI 48864

Telephone: (517) 347-4100
Facsimile: (517) 347-4103

## CLAIMS APPENDIX

4. A composition consisting of a single naturally occurring 16 (±4) kDa protein antigen isolated from *Sarcocystis neurona* and a single naturally occurring 30 (±4) kDa protein antigen isolated from *Sarcocystis neurona* in a pharmaceutically accepted carrier.

13. A method for treating an equine with a *Sarcocystis neurona* infection comprising:

(a) providing a composition consisting of a single naturally occurring 16 (±4) kDa protein antigen isolated from *Sarcocystis neurona* and a single naturally occurring 30 (±4) kDa protein antigen isolated from *Sarcocystis neurona* in a pharmaceutically accepted carrier; and

(b) inoculating the equine with the composition to treat the equine with the *Sarcocystis neurona* infection.

46. A method for treating a disease in an equine caused by a *Sarcocystis neurona* infection which comprises providing a composition which when injected into the equine causes the equine to produce antibodies against a 16 (±4) kDa antigen and a 30 (±4) kDa antigen of the *Sarcocystis neurona* which treats the disease caused by the *Sarcocystis neurona*, wherein the composition consists of a single naturally occurring 16 (±4) kDa protein antigen isolated from *Sarcocystis neurona* and a single naturally occurring 30 (±4) kDa protein antigen isolated from *Sarcocystis neurona* in a pharmaceutically accepted carrier.

50. The method of Claim 46 wherein the composition is administered by an inoculation route selected from the group consisting of intranasal administration, intramuscular injection, intraperitoneal injection, intradermal injection, and subcutaneous injection.